

# Notice of Allowability



Application No.

09/783,969

Examiner

Vickie Kim

Applicant(s)

SHERMAN, BERNARD CHARLES

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to examiner's amendment requested on 7/8/03.
2. ☒ The allowed claim(s) is/are 1, 17, 19-22, 24 and 25.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 09/403,660.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____    |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____               | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment         |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9 <input type="checkbox"/> Other   |

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Hughes, Neil on July 08, 2003.

The application has been amended as follows:

a. Rewrite the claim 1 as follows:

---- Claim 1.(currently amended) A pharmaceutical composition of microemulsion preconcentrate consisting essentially of a cyclosporin dissolved in a solvent system consisting of a fully acetylated monoglyceride lipophilic solvent having a minimum accetylation of 96%, a hydrophilic organic solvent and a synergistic mixture of two surfactants, wherein the microemulsion preconcentrate yields a droplet size in an emulsion of less than 2000 Å as measured by light transmittance through a cell. -----

b. Claim 15. cancelled.

c. In claim 17, line 1, replace [claim 15] with --claim 1 ---- right before "wherein".

d. Claim 18. cancelled.

e. Rewrite the claim 19 as follows:

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---- Claim 19. (currently amended) The composition of claim 1 wherein said two surfactants are selected from a group consisting of one of which is a polyoxyethylene glycolated natural or hydrogenated vegetable oil and the second of which is a polyoxyethylene-sorbitan-fatty acid ester. ---

f. In claim 20, lines 1-2, replace [claim 15 further comprising a ] with --claim 1 wherein the ---- right before "hydrophilic" and insert --- is -- right before "miscible" .

g. In claim 21, line 2, insert -- consisting --- right after "group".

h. In claim 22, lines 1-2, delete [at least] right before "two surfactants" and insert --- consisting --- right after "group".

i. Claims 23. cancelled.

f. Rewrite the claims 24-25 as follows:

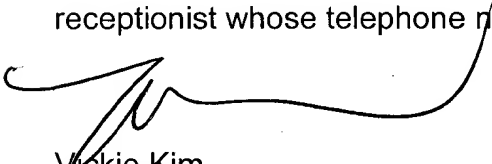
----Claim 24. (currently amended) A pharmaceutical composition of microemulsion concentrate consisting of cyclosporine, a fully acetylated monoglyceride having a minimum acetylation of 96%, propylene glycol, and a synergistic mixture of polyoxyl 40 hydrogenated castor oil and polyoxyethylene 20 sorbitan monolaurate. ---

---- Claim 25. (currently amended) A pharmaceutical composition of microemulsion concentrate consisting of cyclosporine, a fully acetylated monoglyceride having a minimum acetylation of 96%, propylene carbonate, and a synergistic mixture of polyoxyl 40 hydrogenated castor oil and polyoxyethylene 20 sorbitan monolaurate. ---

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**Conclusion**

2. All pending claims 1, 17, 19-22 and 24-25 are allowed.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,  
Patent examiner  
July 14, 2003  
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